



The Natural Choice™

June 6, 1997

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Dockets Management Branch (HFA-305)  
Food and Drug Administration  
12420 Parklawn Drive, Rm. 1-23  
Rockville, MD 20857

**Nature's Way comments regarding: Proposed Rules for Current Good Manufacturing Practice in Manufacturing, Packaging, or Holding Dietary Supplements, Docket No. 96N-0417.**

Nature's Way agrees with the FDA institute rulemaking to develop current good manufacturing practice (CGMP) regulations for dietary supplements and dietary supplement ingredients. Nature's Way feels that the current industry draft is appropriate for CGMP regulations on dietary supplements and dietary supplement ingredients.

Nature's Way offers the comments on the following issues as requested by the FDA on February 6, 1997:

**1. Defect Action Levels**

Nature's Way believes that the current DAL's for foods would not be appropriate for dietary supplements.

**2. Testing Requirements for Ingredient Identification**

Nature's Way believes that organoleptic and morphological characteristics are appropriate identification methods in some cases. However, a company should require additional testing methods (e.g., TLC, HPLC, Microscopic) when organoleptic and morphological characteristics are not adequate.

**3. Contamination, Quality, and Identification Criteria**

Nature's Way believes there is no need for further comments or standards; this topic is already adequately covered in the section on Production and Process controls, subsection (c), numbers 1-7 of the industry draft proposal for CGMP's.

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4. **Documentation Procedures**

Nature's Way believes that as part of an on-going Quality Assurance Program, CGMP procedures and mechanisms for guaranteeing product quality and safety should be audited by the internal quality assurance personnel for regulatory compliance.

5. **Adverse Event Reporting**

Nature's Way believes it is desirable that a firm establish an internal procedure providing for the review of serious adverse reactions by a qualified health care practitioner, as appropriate. Initial review for determination of severity can be done by qualified QC personnel and referred when appropriate.

6. **Relevance of HACCP**

Nature's Way believes that HACCP is not the best means for manufacturing and handling of dietary products.

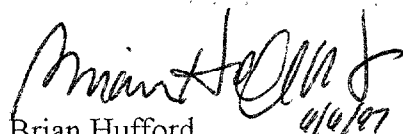
7. **Controls for Computer Assisted Operations**

Nature's Way believes that a computer systems should be verified versus its intended use.

8. **Appropriateness of Broad CGMP Regulations**

Nature's Way believes that the Dietary Supplement Industry Draft provides adequate regulation to all segments of the industry.

Respectfully submitted,



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